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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/236,402	05/02/94	DEAN	R 91875B

EXAMINER

ART UNIT | PAPER NUMBER

1811 | 14

DATE MAILED: 10/29/97

18N2/1029
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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 6/23/97 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire _____ month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-23 are pending in the application.
   Of the above, claims 7, 8, 11-17 and 22-23 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-6, 9, 10, 18-21 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-6,9,10 and 19-21, drawn to a reagent for preparing a scintigraphic imaging agent having amino acid sequences, classified in Class 530, subclass 330.

Group II. Claims 7,8, 11-14,22 and 23, drawn to a complex comprising a reagent for scintigraphic imaging and a radionuclide, classified in Class 424, subclass 1.69.

Group III. Claims 15 and 16, drawn to a method of labeling a reagent, classified in Class 424, subclass 1.11.

Group IV. Claims 17, drawn to a method of imaging, classified in Class 424, subclass 9.1.

Group V. Claim 18, drawn to a composition of matter, classified in Class 530, subclass 335.

Inventions III and IV are distinct from each other because of the different materials, steps, and conditions necessary to perform each method. For example, Group III requires a reacting a labeling agent with a radiolabel in the presence of a reducing agent while Group IV requires a means for obtaining an image of a mammalian body by administering a effective diagnostic amount.

Inventions II and III-IV are related as product and process of use. The inventions

can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product can be used in a method of imaging, as a heavy metal scavenging agent, or as a therapeutic radiopharmaceutical.

Inventions I-V and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as in anyone of the final products, i.e., a radiolabeled complex, a kit for preparing a radiolabeled pharmaceutical, or a radiolabeled imaging agent, and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the process of labeling a reagent with a radiolabel can be performed with many different reagents such as non-peptide organic compounds such as chelating agents, antibodies, etc.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

During a telephone conversation with Kevin E. Noonan on November 8, 1995 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6, 9, 10, and 19-21. Affirmation of this election must be made by applicant in responding to this Office action. Claims 7, 8, 11-18, 22 and 23 withdrawn from further

consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986).

Among these factors are:

1) the nature of the invention,

2) the state of the prior art,

3) the predictability or lack thereof in the art,

4) the breadth of the claims

5) the amount of direction or guidance present, and

6) the presence or absence of working examples.

The following is an analysis of these factors in relationship to this application.

Nature of Invention

The nature of the instant invention is drawn to a reagent for preparing a scintigraphic imaging agent having an amino acid sequence.

State of the Art

There are various patents which describe compounds for Tc-99m or radiolabeled radiodiagnostic imaging. Many of the prior art compounds contain protected cysteine or sulfur containing moieties. See references such as patent nos. 4,434,151; 4,444,690; 4,472,509; and 4,861,868.

Predictability

Peptides are well known in the peptide/protein are area to be unpredictable. See In re Fisher, 57 CCPA 1099, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970).

Breath of Claims

The reagent of claim 1 is indefinite. There is not further guidance as to what the amino acids are and what the final structure will constitute. Applicant claims a specific binding compound. The many possible compounds and complexing moieties that could be produced from the generic description set forth are quite numerous. Applicant has not provided sufficient guidance as to how to identify the amino acids necessary to obtain the desired specific binding compounds or complexing moieties. Applicant has not set forth the process or steps to determine the compounds that specifically binds to the target site to be imaged. Applicant has not demonstrated sufficient representative examples of the "radiolabel complexing moiety" of formula I or II which are broader than the enabling disclosure. Applicant's examples only demonstrate one thiol-containing moiety, which is cysteine. There are no representative examples of homocysteine, isocysteine, 3-mercaptopropylamine, etc. The only amino acids, 1 and 2, demonstrated in the examples set forth are glycine and lysine. See tables I-IV. The amino acids Lys and Gly are not representative of the "any primary α- or β- amino acid that does not comprise a thiol group" as set forth in the generic claims. Does the amino acid linker effect the Biological activity of the reagent? The instant generic compounds are broader than the enabling disclosure. The prior art states: "The efficacy of radionuclides in vivo diagnostic and therapeutic applications depends on the ability to deliver the radionuclide to the site of

the target cells." (see use patent 4,861,869 (Nicolotti et al.) column 1, lines 20-25) Applicants' examples are not sufficient to ensure that the claimed generic reagents would be accepted by one of skill in the art as representative of the instant invention, in view of the breadth of the instant claims.

Guidance

Applicant has failed to provide the proper and sufficient guidance in the specification to enable the instant claims. See the discussion above in the Breadth section.

Representative Examples

Applicant has failed to provide sufficient representative examples to enable the instant invention claims. See discussion in the Breadth Section.

With respect to the adequacy of disclosure that a claimed genus possesses an asserted utility representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if it would be deemed likely by one skilled in the art, in view of contemporary knowledge in the art, that the claimed genus would possess the asserted utility. In re Oppenauer, 31 CCPA 1248, 143 F.2d 974, 62 USPQ 297; In re Cavallito et al., 48 CCPA 711, 282 F.2d 357, 127 UDPQ 202.

For a disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of a claim will possess the alleged utility. See In re Riat et al. (CCPA 1964) 327 685, 140 USPQ 471. In re Barr et al. (CCPA 1971) 444 F 2d349, 151 USPQ 724.

In view of the above it is the Examiner's position that one skilled in the art could

not make and/or use the invention without undue experimentation.

Claims 1-6, 9, 10 and 19-21 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport whose telephone number is (703) 308-4002. The examiner can normally be reached on Tuesday-Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Beth Weimar, can be reached on (703) 308-0254. The fax telephone number for this group is (703) 305-7401 or (703) 305-7362.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Davenport/tf
January 29, 1996

AVIS M. DAVENPORT
PATENT EXAMINER
GROUP 1800